

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DIRECTOR OF HEALTH
DEPARTMENT OF HEALTH
DIVISION OF FACILITIES REGULATION

IN THE MATTER OF:
RHODE ISLAND HOSPITAL

ADDENDUM FOR CLARIFICATION
IMMEDIATE COMPLIANCE ORDER

Now comes the Director of Health of the State of Rhode Island, and pursuant to Rhode Island General Laws, section 23-17-21 makes the following Findings and enters the following Order:

1. Rhode Island Hospital (hereinafter the “hospital”) is a hospital located on Eddy Street in the City of Providence, County of Providence, State of Rhode Island, which is a licensed as a Hospital by the Office of Facilities Regulation within the Department of Health of the State of Rhode Island pursuant to section 23-17-1, et seq of the General Laws of the State of Rhode Island.
2. Pursuant to regulation and as a condition of its license, the Hospital is required to provide care and services in accordance with written policies and procedures pertaining to invasive procedures. The Hospital is further required to comply with all rules and regulations requiring the provision of care and services to all patients in accordance with the prevailing community standard of care and in a manner that maintains the health and safety of individuals, and to ensure that patients do not undergo unnecessary and/or unwanted procedures
3. A review by the Department of Health, on 21 February 2007, indicated that the Hospital failed to provide care and services in accordance with written policies and procedures pertaining to invasive procedures, and failed to provide care and services in accordance with the prevailing community standard of care in a manner that maintains the health and safety of individuals and services. The hospital further failed to ensure that each patient receiving neurology care does not undergo unnecessary and/or unwanted procedures.
4. A review by the Department of Health, on 1 August 2007, of a hospital report concerning MR# 12498739, indicates the hospital has continued to fail to provide neurosurgery care and services in accordance with written policies

and procedures pertaining to invasive procedures, and continued to fail to provide care and services in accordance with the prevailing community standard of care in a manner that maintains the health and safety of individuals, and continued to fail to ensure that each patient receiving neurosurgery care and services does not undergo unnecessary and/or unwanted procedures.

5. Specifically, an 86 year-old male patient underwent a wrong sided craniotomy for the repair of a subdural hematoma on 30 July 2007. An initial review of this incident reveals hospital surgical safeguards are deficient and that some systems were not followed.
6. The Director hereby finds that, based on the continued failure to provide adequate care to patients receiving neurological surgery, the Hospital is not in conformance with the requirements of licensure.
7. The Director hereby finds that the provision of services in accordance with written policy and procedure and in accordance with the prevailing community standard of care, and ensuring each patient does not undergo unnecessary and/or unwanted invasive procedures is essential to maintain each patient's maximum health, safety and welfare.
8. Therefore, based on the foregoing, the Director finds that without intervention of the Department of Health and issuance of this Immediate Compliance Order, the health, safety and welfare of the patients of the Hospital will be in jeopardy.

It is hereby **ORDERED**:

1. Rhode Island Hospital is ordered to engage the services of a Quality Monitor who is approved by the Director of Health to perform a root cause analysis of the circumstances surrounding MR #12498739. Additionally, the consultant shall evaluate the efficacy of all neurosurgical safeguard measures including the following:
 - a. Measures designed to insure correct surgical site and patient identification, and to make recommendation to the Hospital and to the Director for correction.
 - b. Efficacy of electronic imaging in the operating room for intra-operative visualization.
 - c. Overall communication between emergency department and operating room nurses prior to the commencement of a surgical procedure.

2. Rhode Island Hospital is ordered to incorporate a system of double checking correct surgical site identification with two physicians with an unrestricted medical license who must each sign and document the identification of the surgical site immediately prior to initiating the procedure.
3. This Immediate Compliance Order shall be effective immediately upon service.

Entered this 2nd day of August, 2007

By _____
David R. Gifford, MD, MPH
Director of Health, State of Rhode Island

CERTIFICATION OF SERVICE

A copy of the within Immediate Compliance Order was faxed delivered to Kenneth Arnold, Esq., LifeSpan General Counsel by the undersigned on the 2nd day of August, 2007 at 4:30 pm.
